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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,763	07/19/2004	Gunter Holzemann	MERCK-2903	3011

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EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

MAIL DATE	DELIVERY MODE
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01/15/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/501,763

Applicant(s)

HOLZEMANN ET AL.

Examiner

Celia Chang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 11-18 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) 11, 13, 14, 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 12, 16 and 21-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Amendment and response filed by applicants dated Oct. 18, 2007 have been entered and considered carefully.

Claims 8-10, 15, 19-20 have been canceled. Claims 13-14, 17-18 stayed withdrawn. Claims 21-24 are newly added. Claims 1-7, 11-12, 16, 21-24 are pending. Applicants have amended claim 11 to be multiple component composition which have been withdrawn from prosecution. Continued prosecution of claims 1-7, 12, 16, 21-24

2. No certified translation of the priority document was submitted. The effective filing date for the instant application is the PCT filing dated of 17 December, 2002.

3. The rejection of claims 1-7 under 35 USC 112 second paragraph is withdrawn in view of the deletion of the term derivatives.

4. The rejection of claims 1-12, 15-16 under 35 USC 112 first paragraph are now applicable to the newly added claims 21-24 necessitated by such addition.

Applicants argued that just because making hydrates/solvates is a nightmare to one having ordinary skill it does not possess undue experimentation to persons having ordinary skill in the art to make them. This argument is self contradictory. The Braga reference showed that the state of the art is that in so far as hydrate/solvate of a compound is concerned what one possess is what you can make, what one does not possess there is no prediction. In other words, at the time the invention was made, if the specification possesses no solvates, no process in the art can support how to make any. The specification provided no solvates.

Further, the specification provided no enablement as to how to obtain "isolated" stereoisomer of any compound of formula I. Please note that the specification provided no description as to where structurally a stereo-isomer can be formed i.e. *cis*-, *trans*-, *chiral* etc. or how to isolate such un-described isomers. While one can possess mixtures of isomers occur naturally during synthesis, such possession does not support "isolated" stereoisomer when the kinds of isomer or how to isolate them finds no description and enablement in the specification.

Stereoisomer separation can be extremely unpredictable due to its empirical nature (see Morrison p.3).

5. The rejection of claims 1-6, 11-12, 15-16 under 35 USC 103(a) over Baumgarth et al. EP 649,838 supplemented with CA 123 in view of Doughty et al. US 2004/0180401 is now applicable to the amended and newly added pending claims 1-7, 12, 16, 21-24.

Initially, it is noted that there is no 102 rejections only 103(a) rejection. Further, the examiner did not understand applicants' arguments of pages 10-12.

The rejection is an obviousness rejection because the Baumgarth '838 "generically" disclosed the claims i.e. formula I when Ar and Ar' are independent substituted with Hal, CF<sub>3</sub>, NO<sub>2</sub> or NHSO<sub>2</sub>A, etc. The exemplification of Ar and Ar' substituted with identical choice of substituents (see RN 167859-10-1; 167858-76-7; 167859-05-4 of the reference delineated by CAS) and the explicit intermediates (see 86518-58-3) rendered the instant claims which are limiting Baumgarth 's formula I to Ar' is always substituted with NHSO<sub>2</sub>A and Ar is substituted with NO<sub>2</sub>, Hal, CF<sub>3</sub> etc. obvious. The Doughty '401 reference is providing evidence that symmetrically substitution of Ar and Ar'; and asymmetrical substitution of Ar and Ar' are considered "analogous" art and are expected to have similar biological activity. In other words, the exemplified compounds and intermediates rendered the unexemplified broader scope (which is the instant claims) obvious. The '401 reference is supporting evidence that the exemplified and unexemplified scope of Baumgarth '838 would be expected to have similar activity, thus, successful in operation.

In addition, with the explicit exemplification of RN 86518-58-3, and the synthesis of RN 167859-10-1; 167858-76-7; 167859-05-4, it would render the instantly amended claim 7 obvious since the operable procedure and the intermediates are explicitly disclosed even though the product was not delineated.

6. Applicants amendment necessitated the modification and extension of the rejections of record. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
Jan. 9, 2008

  
Celia Chang  
Primary Examiner  
Art Unit 1625